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Atty. Docket No. 4506-1025
PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	Appeal No. _____
Carl Ernest ALEXANDER et al.	Conf. 2239
Serial No. 10/766,912	Group 1612
Filed January 30, 2004	Examiner Lezah Roberts

PERSONAL CARE COMPOSITIONS WITH PORTABLE PACKS

APPEAL BRIEF

MAY IT PLEASE YOUR HONORS:

Applicants respectfully appeal the Final Rejection of claims 1, 3-4, 7-8, 13, 23-28, 30 and 34 as unpatentable under 35 U.S.C. 103(a) as set forth in the Official Action mailed May 26, 2010.

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(i) Real Party in Interest

The real party in interest in this appeal is the assignee, PBL TECHNOLOGY LIMITED, of Auckland, NEW ZEALAND.

(ii) Related Appeals and Interferences

None.

(iii) Status of Claims

Claims 1, 3-4, 7-8, 13, 23-28, 30 and 34 are pending, from whose final rejection this appeal is taken.

Claims 2, 5-6, 9, 12, 14-17, 19-22, 32-33 are cancelled.

Claims 10, 11, 18, 29 and 31-33 are withdrawn from consideration.

The final rejection of claims 1, 3-4, 7-8, 13, 23-28, 30 and 34 is being appealed.

In addition, claims 1, 3-4, 7-8, 13, 23-28, 30 and 34 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of co-pending Application No. 12/067,817. However, because this rejection has been indicated as provisional, and further because co-pending Application No. 12/067,817 has not gone to patent as of the time of the writing of this Appeal Brief, the rejection on the ground of nonstatutory obviousness-type double patenting is not the subject of this Appeal. Appellants will reconsider this rejection upon re-opening of prosecution.

(iv) Status of Amendments

There are no outstanding amendments.

The claims have not been amended since an amendment submitted by the Appellant on February 2, 2010 (the "Amendment").

These claims were finally rejected by the Official Action mailed May 26, 2010 (the "Official Action").

(v) Summary of Claimed Subject Matter

The invention is directed toward a semi-solid composition formed into discrete, soft, and homogenous semi-solid beads suitable for use in personal oral, dental, or skin care, wherein the composition comprises a semi-solid gel comprising at least one pharmaceutically acceptable active ingredient intimately mixed with at least one gelling agent.

Figure 2 of the application illustrates some exemplary embodiments of the invention, and Figure 1b further illustrates the invention packaged within blister packs.

Claims 1, 23 and 30 are independent. Claims 1, 23 and 30 recite embodiments of the semi-solid composition according to the invention.

Independent Claim 1

As recited by claim 1, the invention is a semi-solid composition for use in single-dose form in personal oral, dental, or skin care (page 5, lines 18-19; page 12, lines 3-9; Figure 2, elements 200, 202-204), the composition comprising i) a gelling agent comprising agar (page 5, line 21; page 6, lines 16-18), and ii) an active ingredient intimately mixed with said gelling agent (page 5, line 21),

wherein said gelling agent and said active ingredient are intimately mixed and form a homogeneous and non-encapsulated single-dose gel bead (page 3, lines 21-26;

page 5, line 21; page 12, lines 9-10; Figure 2, element 201) including between 0.5 and 1.2 percent agar by weight (page 6, lines 16-18),

wherein the gel bead has a mass between 0.25 and 2.0 grams (page 7, line 2),

wherein the gel bead has a compact, stable shape (page 5, lines 8-11; page 6, lines 6-8; Figure 2, elements 200, 202-204), and

wherein the gelling agent of the gel bead has a gel framework formed about the active ingredient, the gelling agent of the gel framework having a concentration such that the gel framework will break apart and release the active ingredient when the gel bead is disrupted by a person in a personal oral, dental, or skin care procedure (page 4, lines 13-30; page 5, lines 22-26; page 6, lines 6-8; page 12, lines 17-19).

Independent Claim 23

Another embodiment of the invention, as recited by claim 23, is a semi-solid homogeneous gel bead (page 3, lines 21-26) for use in single-dose form in personal oral, dental or skin care (page 1, lines 4-7; page 5, lines 18-19; page 6, line 30 to page 7, line 2), comprising i) a gelling agent (page 4, lines 13-30; page 5, lines 20-21) and ii) an active ingredient intimately mixed with said gelling agent to form a

mixed homogeneous composition of said gelling agent and said active ingredient (page 5, lines 20-21; page 12, lines 9-10; Figure 2, element 201),

wherein said gelling agent having a gel framework containing the active ingredient (page 5, lines 22-24; page 12, lines 17-19),

wherein the gelling agent has a concentration such that the gel framework of the gelling agent has a semi-solid state (page 5, lines 27-29), and such that the gelling agent will break apart and release said active ingredient upon being forcibly disrupted by a person in any of an oral, dental, or skin care procedure (page 5, lines 24-26; page 5, line 29 to page 6, line 2; page 6, lines 6-8; page 12, lines 17-19), and

wherein the gelling framework, in the semi-solid state, is formed as a bead (page 3, lines 21-26; page 6, lines 9-14; page 6, line 30 to page 7, line 2; page 12, lines 9-10; Figure 2, element 201).

Independent Claim 30

Yet another embodiment of the invention, as recited by claim 30, is a semi-solid composition for use in single-dose form in personal oral, dental, or skin care (page 5, lines 18-19; page 12, lines 3-9; Figure 2, elements 200, 202-204), the composition comprising a homogenous and non-encapsulated single-dose gel bead comprised of a single dose

of an active ingredient intimately mixed with a gelling agent (page 3, lines 21-26; page 5, line 21; page 12, lines 9-10; Figure 2, element 201),

wherein the gelling agent comprises carrageenan (page 4, lines 13-30; page 6, lines 19-20),

wherein the bead has a mass between 0.25 and 2.0 grams (page 7, line 2),

wherein the bead has a compact, stable shape (page 5, lines 8-11; page 6, lines 6-8; Figure 2, elements 200, 202-204),

wherein the bead has an homogenous composition including between 0.1 and 4 percent carrageenan by weight (page 6, lines 19-20), and

the gelling agent providing a gel framework about the active ingredient, the gelling agent having a concentration such that the gel framework breaks apart and releases the active ingredient upon the gel bead being forcibly disrupted by a person in a personal oral or dental procedure (page 4, lines 13-30; page 5, lines 22-26; page 6, lines 6-8; page 12, lines 17-19).

(vi) Grounds of Rejection to be Reviewed on Appeal

The sole Ground of Rejection on appeal is whether claims 1, 3-4, 7-8, 13, 23-28 and 30 were properly rejected as unpatentable under § 103(a) over Schmidt (U.S. Patent 5,354,551; hereinafter "SCHMIDT") in view of Alexander (WO 2002/026078, English Equivalent U.S. Publication 2004/0091431; hereinafter "ALEXANDER") and Grossmith (GB 750,126; hereinafter "GROSSMITH").

(vii) Arguments

Arguments Concerning the Sole Ground of Rejection

Independent claims 1, 23, and 30 stand together.

Independent claims 1, 23, and 30 were rejected under § 103(a) as unpatentable over SCHMIDT in view of ALEXANDER and GROSSMITH.

The present invention is directed to a semi-solid gel bead comprising a pharmaceutically acceptable active ingredient intimately mixed with a gelling agent. The claims particularly recite either agar or carrageenan as the gelling agent. The gelling agent and the active ingredient are intimately mixed and form a homogeneous and non-encapsulated single-dose gel bead, such as to form a uniform composition in cross-section (page 12, lines 9-10; Figure 2 elements 200 and 201). The gelling agent is present at a concentration at least high enough to cause the composition to remain in a semi-solid state when held at a storage temperature, but also sufficiently low to permit the semi-solid composition to break apart and render the at least one active ingredient available when disrupted by a user in, for example, a dental or other personal care procedure (see, e.g., specification at page 5 line 18 to page 7 line 8).

Any one bead is capable of providing sufficient active ingredients for a single oral, dental, or skin care procedure. Further, as a consequence of the semi-solid composition, each bead may be shape adapted to, for example, be held by the bristles of a tooth brush (Figure 2, elements 202 and 208), and/or be shaped, colored, and/or flavored to be particularly appealing to children (page 7, lines 9-19). In the latter case, the single-dose configuration helps to prevent accidental overdosing, where children would otherwise be required to measure out an amount of product for themselves.

No prior art is known to anticipate the invention as claimed. The Examiner rejects the claims as being obvious in view of a combination of prior art references.

Particularly, the Examiner offers SCHMIDT as teaching a semi-solid, homogeneous composition comprising a gelling agent and a single-dose of active ingredient, but concedes that the reference fails to teach either of i) a bead shape, or ii) gelling agents of either agar or carrageenan.

The Examiner offers ALEXANDER as teaching a bead shape, and GROSSMITH as teaching the agar and carrageenan, and therefore alleges that the invention would have been obvious.

The Examiner's rejection, however, is fatally flawed because neither of ALEXANDER or GROSSMITH is reasonably

combinable with SCHMIDT. That is, the rejection is the result of an improper application of hindsight as there would have been no reasonable motivation for one of skill in the art to have modified SCHMIDT with ALEXANDER and GROSSMITH as proposed by the Examiner, and even if the references were so combined, the result fails to teach or suggest the claimed invention.

SCHMIDT and ALEXANDER Are Not Combinable

The Examiner offers SCHMIDT as teaching a semi-solid composition comprising a gelling-agent. However, as conceded by the Examiner, SCHMIDT is directed to a gelling-agent formed as a thin film or foil (column 1, lines 60-65; column 2, lines 28-47), and makes no teaching or suggestion that the composition is formulated for single-dose beads.

The Examiner offers ALEXANDER as teaching a single-dose dental hygiene product in the form of a bead. On page 5 of the non-final Office Action of October 2, 2009, the Examiner conceded that the ALEXANDER bead contrasts sharply with the bead of the invention, as the ALEXANDER bead comprises a paste contained within a wall or shell having a dry exterior (paragraph [0008]). Particularly, it is noted that the shell is configured to be water-soluble from the outside but water impermeable from the inside, portions of which are expected to remain un-dissolved at the conclusion of tooth-brushing and discarded (paragraph [0072]).

Instead, the Examiner's case for obviousness depends on the allegation that one of skill would have been motivated by ALEXANDER to modify the film formulation of SCHMIDT into the form of a bead.

Respectfully, the Examiner's position is not reasonable. Particularly, the Examiner fails to consider the properties of SCHMIDT's gel composition as particularly designed for dissolution when exposed to moisture. The Examiner makes the mistake of assuming that all gel compositions are created equal and, further, that one shape is as effective as another. However, there is no evidence presented that would teach or suggest to one of skill in the art that forming SCHMIDT's thin foil strips into bead-shapes would have had a reasonable chance of success. On the contrary, it is evident that the modification proposed by the Examiner would defeat the intended function of SCHMIDT.

SCHMIDT's composition formulated to be provided as strips with a thickness of 0.1 to 3mm, pre-segmented into dosage units corresponding to the size of a toothbrush (column 2, lines 40-55). The activating agent is moisture, first provided by a wetted toothbrush, and then the saliva of the user, in order for the payload ingredient to disperse and "develop their full activity," (column 3, lines 4-10). The

foil shape of SCHMIDT offers the greatest possible surface area for moisture contact.

Replacing SCHMIDT's foil shape with a bead shape reduces the effective surface area available for moisture contact from maximal to minimal, thereby having a detrimental effect on the speed and efficiency with which SCHMIDT's gel composition will dissolve, and thereby reducing the utility and effectiveness of the product in both its use as a tooth-cleaning product and its attractiveness as an alternative to traditional toothpaste. Accordingly, the proposed modification renders SCHMIDT unsatisfactory and would have been non-obvious and, indeed, counter-intuitive to one of skill at the time the present invention was made.

SCHMIDT provides active ingredients ready for use as a strip or foil, having a thickness of 0.1-3 mm (column 2, line 48) or as a film of thickness 0.5 mm (column 3, line 52), upon a peelable carrier foil (column 2, line 57) or film made of a disposable substance such as paper. SCHMIDT exclusively refers to the dentifrice as a foil or film (e.g., column 2, line 47), and that it is introduced to the mouth by being placed on a moistened toothbrush (column 3, lines 2-6) which causes dissolution to commence even before the toothbrush enters the user's mouth (column 3, lines 4-5). No time is disclosed as to how long the film takes to completely dissolve

after insertion into the mouth, but is clear that "the intensive movement" of the toothbrush is part of the dissolving process (see column 3, line 8-9).

The actual consistency of the SCHMIDT foil can be derived only indirectly from the description. It is "punchable (column 2, line 50), "perforatable" (column 2, line 50) and "peelable" (column 2, line 65; and column 3, line 2). As such the SCHMIDT foil is clearly tougher, as a foil, than the present invention which is "disruptable" (see, e.g., page 5 line 18 to page 7 line 8 of the instant specification). No indication that the SCHMIDT foil is disruptable in the same way can be found.

SCHMIDT, significantly, does not teach the use of agar (agar-agar) as a disruptable carrier for the active ingredients of a dentifrice. Instead, SCHMIDT relies on a quick dissolving action to distribute its substances (column 1, lines 60-65; column 2, lines 40-42), as would be expected of a broad film one half millimeter thick and exposed on both sides. Although SCHMIDT does not disclose a time for dissolution, the reference suggests that full dissolution requires at least some brush activity (see column 3, line 9). Therefore, dissolution cannot be immediate, which is no surprise given the high concentration of either amylogum or gelatin (column 3, lines 40-48), and given that the product

must i) adhere to the brush prior to insertion into the mouth, but ii) maintain enough structure so as not to completely dissolve prior to the insertion.

One of skill would have readily appreciated that a film having a thickness of 0.5 mm and 35 x 8 mm immersed in water will be completely dissolved once 0.25 mm of material has dissolved from each surface. A shape of a thin strip or film is ideal for this method of dissolution, as a flat composure enables the greatest surface area with respect to a given volume. Indeed, SCHMIDT requires that a dosage of the film is to adhere to the toothbrush and swell once placed onto a moistened toothbrush by means of the moisture contact (column 3, lines 2-6). Thus, SCHMIDT's product pre-dissolves in a first mode, whereas full dissolution takes place afterward so that the components can develop their full activity, and hence, after use and subsequent mouth washing with water, no remains are retained in the mouth (column 3, lines 9-12).

A bead shape would completely defeat this purpose. A sphere or semi-sphere is a shape with a minimized surface area for the volume. That is, the surface area of the strip or film disclosed by SCHMIDT is much greater than that of even a semi-spherical gel having the same volume. Hence, one of skill would appreciate that the rate of dissolution of

SCHMIDT's foil or film is greatly impacted by modifying the shape from a flat profile. SCHMIDT offers nothing that would suggest to one of skill that such a modification would be successful.

Clearly, a spherical shape is the worst possible shape with which to modify SCHMIDT given SCHMIDT's disclosed necessity for controlled dissolution (partial dissolution on the wet brush, full dissolution in the mouth), and SCHMIDT's disclosed relationship between dissolution and exposed surface area. In experiments performed by Mr. Patrick Silcock, reported in a Declaration submitted in compliance with 37 C.F.R. 132 on February 2, 2010, no benefit was drawn from forming SCHMIDT into the form of a bead (see Declaration of Patrick Joseph Silcock, page 8, lines 10-12). Indeed, according to the Declaration by Mr. Silcock as provided in the Appendix to this paper, one of skill would have found no teaching toward a satisfactory result by either of SCHMIDT or any combination of SCHMIDT with ALEXANDER.

One of skill would therefore reasonably conclude that SCHMIDT, modified to take the form of a spherical or semi-spherical bead, would fail to properly dissolve to adhere to the toothbrush (and, e.g., fall off the toothbrush), and would further fail to completely dissolve in the mouth within a reasonable amount of brushing time (leaving undissolved

residue, wasted and unpleasant as it rolls around loosely in the mouth cavity). This result would clearly have been an unsatisfactory result in view of the teachings of SCHMIDT.

SCHMIDT is further detrimental to ALEXANDER in that its property of being rapidly dissolved by moisture-exposure leads to stickiness and microbial spoilage while in storage. ALEXANDER overcomes or mitigates these issues with its semi-solid outer shell. The combination as proposed to replace the composition of ALEXANDER with the composition of SCHMIDT formed as a bead would eliminate the advantages of ALEXANDER's shell and re-introduce the problems of poor shelf-life due to unintentional moisture exposure and spoilage through bacterial contamination.

Obviousness does not exist where a combination of references would render the prior art unsatisfactory for its intended purpose (see MPEP § 2143.01). Therefore, the proposed modification of SCHMIDT with ALEXANDER fails to render as obvious the invention recited in the independent claims 1, 23, and 30, at least because no reasonable motivation would have existed for one of skill to have combined the references SCHMIDT and ALEXANDER as proposed by the Examiner.

SCHMIDT, ALEXANDER Are Not Combinable With GROSSMITH

The Examiner concedes that neither of SCHMIDT and ALEXANDER, individually or in combination, teaches or suggests a gelling agent comprising agar or carrageenan, as recited by claims 1, 24-25, 30 and 31.

The Examiner offers GROSSMITH as teaching agar and carrageenan as gelling agents. However, none of the compositions formed of agar or carrageenan disclosed by GROSSMITH teaches or suggests semi-solid beads as recited by the independent claims.

This is not contested; the Examiner, on page 6 of the February 10 Official Action, conceded that GROSSMITH does not disclose the compositions are formulated into single-dose beads as an oral or dental composition. However, the Examiner maintains it would have been obvious to one of ordinary skill in the art to have used agar or carrageenan as taught by GROSSMITH as the gel forming agent(s) in the compositions of the combined teachings of SCHMIDT and ALEXANDER, motivated by the desire to make single dose gel beads having good strength with good suspending power and temperature stability and low solid content with strong structure, based on the teachings of GROSSMITH.

GROSSMITH describes some properties of agar-agar, such as when in "an aqueous solution at a high concentration"

it "cannot be readily squeezed from tubes" (page 1, lines 50-55). In particular, GROSSMITH sets out to improve on the inherent properties of agar-agar. However, it must be noted that the teachings of GROSSMITH solely relate to the preparation of a reaction product made by "mixing at least two different carbohydrate complexes or derivatives together at an elevated temperature in a aqueous medium" (claim 1, at page 3, line 61 and up to final claim 8, at page 3, line 98, and further throughout the text of the reference). Such a process is not pertinent to the present application. GROSSMITH does not disclose any process in which, as per the present application, a single carbohydrate complex or derivative is heated in an aqueous solution.

Further, apart from teaching that processed combinations of agar and carrageenan are suitable as jellies or viscous solutions to be used as hand jellies, stabilizers, detergent builders, and vehicles for medicaments (page 1, lines 10-14), GROSSMITH offers no teaching or suggestion that would lead one of skill in the art to reasonably believe that modifying either SCHMIDT or a combination of SCHMIDT with ALEXANDER would be remotely successful. SCHMIDT is directed to a foil strip configured to dissolve on the toothbrush and in the mouth upon the application of moisture. ALEXANDER is a bead-shaped shell encapsulating a liquid or viscous payload.

In stark contrast, GROSSMITH is unequivocally directed toward far softer compositions with a texture "for filling into tubes or pots," (page 2, lines 49-50). Of the uses and application disclosed in the list on page 3, lines 21-45, not one suggests a semi-solid bead. All of them, instead, are soft, liquid-like compositions of various viscosities, e.g., hand jelly, tooth paste, shampoo, creams, pastes, suspension jellies for food, surgical lubricant, culture medium for bacteriology, lotions, and thickeners for ice-cream and jams (page 3, lines 21-45).

Thus, the Examiner asserts one of skill would have been motivated to modify the semi-solid foil of SCHMIDT with a jelly with the consistency of a cream or a paste. It would be clear to one of skill, however, that whether shaped as a strip or shaped as a bead, a creamy or pasty composition would have rendered SCHMIDT unsatisfactory. On the contrary, the combination would yield an invention akin to a dose of ordinary toothpaste, the very product SCHMIDT intended to improve upon.

Further, GROSSMITH fails to teach or suggest "semi-solid composition" and "bead" as recited in the claims. In particular, the compositions disclosed of both agar-agar (Examples I, II, and IV of pages 2 and 3) and carrageenan

(Example III of page 2) are unequivocally directed toward a "jelly of somewhat short texture" (page 2, lines 65).

In contrast, the specification as originally filed defines semi-solid as "easily deformed by an applied force, yet retains a predetermined shape on removal of the force unless deformation exceeds a limit... [t]he force of gravity is less than the limit," (page 5, lines 8-11). The specification further describes the semi-solid composition as "being capable of breaking apart when the composition is forcibly disrupted by a person," (page 5, lines 24-25). None of the compositions taught by GROSSMITH even remotely suggests this feature.

The only pertinent teaching offered by GROSSMITH toward solid or semi-solid properties is a composition of unmodified agar-agar that is described as unsuitable. "Agar-agar itself forms a jelly of somewhat short texture which, when used as a hand jelly, breaks up into fragments which cannot be rubbed satisfactorily into the hands," (page 1, lines 39-43). "When it is employed in an aqueous solution at a high concentration, a jelly which does not liquefy up to about 85 C may be obtained, but such a jelly is so tough at ordinary temperatures that it cannot be readily squeezed from tubes," (page 1, lines 49-55).

However, even this disclosure in GROSSMITH fails to provide any teaching suggesting the semi-solid bead recited in the claims, or would have reasonably motivated one of skill to modify SCHMIDT to incorporate agar. On the contrary, one of skill considering the dissolvable foil of SCHMIDT would have had no use for "a jelly which does not liquefy up to about 85 C" that is "so tough at ordinary temperatures that it cannot be readily squeezed from tubes."

Therefore, as the proposed modification of SCHMIDT with GROSSMITH renders SCHMIDT unsatisfactory for its intended purpose, it is respectfully submitted that it would have been unreasonable for one of skill to have combined the references SCHMIDT, ALEXANDER, and GROSSMITH as alleged by the Examiner. It is further respectfully submitted that as GROSSMITH fails to teach a semi-solid gel bead, either of agar or carrageenan, none of SCHMIDT, ALEXANDER, or GROSSMITH, individually or in combination, teaches or suggests all the features recited in the independent claims 1, 23, and 30.

Based at least on the foregoing reasons, it is respectfully submitted that the proposed combination of SCHMIDT and ALEXANDER with GROSSMITH fails to render as obvious the invention recited in the amended claims.

Conclusion

Based upon all of the foregoing, favorable reconsideration and reversal of the Examiner's rejections of claims 1, 3-4, 7-8, 13, 23-28, 30 and 34 under 35 USC § 103, by the Honorable Board of Patent Appeals and Interferences, are respectfully solicited.

The Appeal Brief fee of $270 is being paid online simultaneously herewith by credit card.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any underpayment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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JGM/lrs
Enclosure: Claims Appendix

(viii) Claims Appendix

1. (previously presented) A semi-solid composition for use in single-dose form in personal oral, dental, or skin care, the composition comprising:

a gelling agent comprising agar; and

an active ingredient intimately mixed with said gelling agent,

wherein said gelling agent and said active ingredient are intimately mixed and form a homogeneous and non-encapsulated single-dose gel bead including between 0.5 and 1.2 percent agar by weight,

wherein the gel bead has a mass between 0.25 and 2.0 grams,

wherein the gel bead has a compact, stable shape, and

wherein the gelling agent of the gel bead has a gel framework formed about the active ingredient, the gelling agent of the gel framework having a concentration such that the gel framework will break apart and release the active ingredient when the gel bead is disrupted by a person in a personal oral, dental, or skin care procedure.

2. (cancelled)

3. (previously presented) The semi-solid composition as claimed in claim 1, wherein the gelling agent includes agar at a concentration in a range of from about 0.1 to about 2 per cent by weight.

4. (previously presented) The semi-solid composition as claimed in claim 1, wherein the gelling agent comprises agar at a concentration in a range of from about 0.3 to about 0.95 per cent by weight.

5-6. (cancelled)

7. (previously presented) The semi-solid composition as claimed in claim 1, wherein the active ingredient is a dentifrice sufficient for a single dental care procedure, the gel framework having a concentration such that the gel framework will disrupted by any of the mouth of the person and against a toothbrush before a brushing procedure begins.

8. (previously presented) The semi-solid composition as claimed in claim 7, wherein the bead has a mass in the range of from about 0.4 gram to about 1 gram.

9. (canceled)

10. (withdrawn) A kit or pack for use in personal care, including at least one bead of a semi-solid gel as claimed in claim 7, wherein the bead is stored within a compartment within the kit or pack, the compartment comprising a depression formed in a deformable sheet, and covering means for covering the depression.

11. (withdrawn) The kit or pack for use in personal care as claimed in claim 10, wherein the pack further provides an application tool including means for contacting a plurality of surfaces of the person's teeth, so that after disruption of a bead and release of the at least one active ingredient adjacent to the teeth, use of the tool promotes cleansing of the teeth.

12. (canceled)

13. (previously presented) The semi-solid composition as claimed in claim 1, wherein the active ingredient comprises an oral disinfectant.

14-17. (canceled)

18. (withdrawn) A kit or pack for use in personal care, comprising:

at least one bead having a semi-solid composition as recited in claim 1;

at least one application tool; and

a blister pack,

wherein the bead and the application tool are contained within corresponding cavities within the blister pack.

19-22. (canceled)

23. (previously presented) A semi-solid homogeneous gel bead for use in single-dose form in personal oral, dental or skin care, comprising:

a gelling agent; and

an active ingredient intimately mixed with said gelling agent to form a mixed homogeneous composition of said gelling agent and said active ingredient,

wherein said gelling agent having a gel framework containing the active ingredient,

wherein the gelling agent has a concentration such that the gel framework of the gelling agent has a semi-solid state, and such that the gelling agent will break apart and

release said active ingredient upon being forcibly disrupted by a person in any of an oral, dental, or skin care procedure, and

wherein the gelling framework, in the semi-solid state, is formed as a bead.

24. (previously presented) The semi-solid bead as claimed in claim 23, wherein said gelling agent includes agar at a concentration ranging between 0.1% by weight to 2% by weight.

25. (previously presented) The semi-solid bead as claimed in claim 23, wherein said gelling agent includes agar at a concentration ranging between 0.3% by weight to 0.95% by weight.

26. (previously presented) The semi-solid bead as claimed in claim 24, wherein said gelling agent further includes gelatin at a concentration ranging between 1% by weight to 4% by weight.

27. (previously presented) The semi-solid bead as claimed in claim 23, wherein the composition has a mass ranging between 0.4 grams to 1 gram.

28. (previously presented) The semi-solid composition as claimed in claim 1, wherein the gelling agent includes agar at a concentration in a range of from about 0.7 to about 0.9 per cent by weight.

29. (withdrawn) The semi-solid composition as claimed in claim 1, wherein the active ingredient comprises a skin care product.

30. (previously presented) A semi-solid composition for use in single-dose form in personal oral, dental, or skin care, the composition comprising:

a homogenous and non-encapsulated single-dose gel bead comprised of a single dose of an active ingredient intimately mixed with a gelling agent, the gelling agent comprising carrageenan,

wherein the bead has a mass between 0.25 and 2.0 grams,

wherein the bead has a compact, stable shape,

wherein the bead has an homogenous composition including between 0.1 and 4 percent carrageenan by weight, and

the gelling agent providing a gel framework about the active ingredient, the gelling agent having a concentration such that the gel framework breaks apart and

releases the active ingredient upon the gel bead being forcibly disrupted by a person in a personal oral or dental procedure.

31. (withdrawn) The semi-solid composition as claimed in claim 1, wherein the bead is formed by the steps of:

fully dissolving a mixture comprising the agar and the active ingredient in hot water at a first temperature of about 95-100 degrees Celsius, the active ingredient being capable of withstanding the first temperature;

cooling the mixture;

adding additional active ingredients inherently unstable at the first temperature;

dispensing the mixture having a molten state in controlled single dose quantities; and

further cooling the mixture to become a semi-solid gel.

32-33. (canceled)

34. (previously presented) The semi-solid composition as claimed in claim 23, wherein the bead has an homogenous composition including between 0.1 and 4 percent carrageenan by weight.

(ix) Evidence Appendix

Declaration of Patrick Joseph Silcock, originally submitted February 2, 2010 in compliance with 37 C.F.R. 132.

(x) Related Proceedings Appendix

None.